K070582



APR 16 2007

## 510(k) SUMMARY

As required by the Safe Medical Devices Act of 1990

### DESCRIPTION OF THE APPLICANT DEVICE

TRADE NAME: Multiple (NANO COMPOSITE)
COMMON NAME: Nano-hybrid Dental Composite
CLASSIFICATION NAME: Tooth Shade Resin Material (21 CFR 872.3690, Product code EBF)

**Cosmedent** NANO COMPOSITE is a light-cure composite resin fabricated from difunctional acrylic monomers and silicaceous fillers. These materials possess physical and mechanical properties that allow them to function in the oral cavity with esthetic qualities that mimic natural tooth appearance.

The technological characteristics of the applicant device are essentially identical to the predicate device.

### IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE

TRADE NAME: Tetric EvoCeram
COMMON NAME: Nano-hybrid Dental Composite
CLASSIFICATION NAME: Tooth Shade Resin Material (21 CFR 872.3690, Product code EBF)
510(k) Number: K042819

### SUBSTANTIAL EQUIVALENCE SUMMARY

| EQUIVALENTS | Cosmedent NANO COMPOSITE | Ivoclar Vivadent TETRIC EVO CERAM |
|---|---|---|
| Intended Use | Similarities | |
| | Both products have identical intended uses as esthetic dental restorative materials | |
| Composition | Both products have substantially the same chemical composition. They are light-cure, silica filled, difunctional acrylic composites | |
| Physical properties | Both products have similar physical and mechanical properties as shown below | |
| How supplied and used | Both products are supplied as preloaded, plastic-screw fed syringes. The material is extruded onto a suitable pad and placed in the prepared cavity and light cured | |
| Mechanical and Physical Properties | Cosmedent NANO COMPOSITE | Ivoclar Vivadent TETRIC EVOCERAM |
| Compressive strength | 400 MPa | 313 MPa |
| Flexural strength | 125 MPa | 120 MPa |
| Modulus of elasticity | 12000 MPa | 9500 |
| Radiopaque | Yes | Yes |
| | Differences | |
| Number of shades | 13 | 16 |

Submitted by: James L. Sandrik, PhD
Cosmedent, Inc.
401 N. Michigan Ave. Suite 2500
Chicago, IL 60611

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

James L. Sandrik, PhD
Director of Regulatory Affairs
Cosmedent, Incorporated
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Chicago, Illinois 60611

APR 16 2007

Re: K070583
Trade/Device Name: Nano Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: February 28, 2007
Received: March 01, 2007

Dear Dr. Sandrik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE

510(k) Number (if known): K070583

Device Name: MULTIPLE (**NANO COMPOSITE**)

Indication For Use:

NANO COMPOSITE is designed for Class I-V dental restorations, direct veneering of anterior teeth, splinting, and repair of composite or ceramic restorations.

Prescription Use___X____ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

...ion Control, Dental Devices

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